REMARKS

In the aforesaid Office Action, claims 11, 13-19, 21-26, 50, 51, 53, 56-60, and 64-65 were rejected under 35 USC §103(a) as being unpatentable over Evard (U.S. Patent No. 5,242,396) in view of Crowley et al. (U.S. Patent No. 6,004,279) and further in view of Berenstein et al. (U.S. Patent No. 5,895,378), claims 11, 13, 16-18, 51 and 56 were rejected under 35 USC §103(a) as being unpatentable over Shank et al. (U.S. Patent No. 5,147,317) in view of Crowley and further in view of Berenstein et al., claim 12 was rejected under 35 USC §103(a) as being unpatentable over Hibbs et al. (U.S. Patent No. 4,950,257) in view of Crowley and further in view of Berenstein et al., and claim 12 was rejected under 35 USC §103(a) as being unpatentable over Evard in view of Crowley and further in view of Berenstein et al. and Maguire et al. (U.S. Patent No. 6,599,288). Claims 11-19, 21-26, 51, 53, 56-60, 64 and 65 are pending.

The Examiner rejected claims 11, 13-19, 21-26, 50, 51, 53, 56-60, and 64-65 under 35 USC §103(a) as being unpatentable over Evard in view of Crowley et al. and further in view of Berenstein et al., and claim 12 under 35 USC §103(a) as being unpatentable over Evard in view of Crowley and further in view of Berenstein et al. and Maguire et al., stating that Evard discloses the invention substantially as claimed but however does not disclose that the proximal section has a crystallinity and the distal section has a second crystallinity lower than the proximal section first crystallinity such that the proximal section is stiffer, and Crowley teaches a metal guidewire wherein the

distal portions are annealed progressively to cause the distal portions to be more flexible than the proximal portions and Berenstein teaches a PVC or polyurethane catheter provided with added flexibility where the catheter is annealed.

However, Crowley and Berenstein teach an annealed section (of a guidewire in Crowely, and of a catheter in Berenstein) which is made more flexible. In contrast, Applicant's claim 1 requires that the non-metal mandrel has an annealed proximal section which is less flexible than the distal section. The Examiner states that it would have been obvious to anneal the distal portions of the Evard plastic mandrel as taught by Crowley in view of Berenstein in order to provide gradual flexibility. However, annealing the distal section of the non-metal mandrel to increase its flexibility does not disclose or suggest the embodiments set forth in Applicant's claims which require that the non-metal mandrel has an annealed proximal section which is less flexible than, or has a higher crystallinity than, the distal section. Thus, Evard in view of Crowley and Berenstein does not disclose or suggest a mandrel comprised of a non-metal material having an annealed proximal section with a first crystallinity and a distal section with a second crystallinity lower than said annealed proximal section first crystallinity.

Regarding claims 16 and 64, Evard in view of Crowley and Berenstein et al. does not disclose or suggest fusion bonding the mandrel to the catheter shaft. The Examiner states that Evard discloses that the mandrel is fixed to the catheter shaft, col. 3, lines 38-39). However, Evard discloses at col. 3, lines 38-39 that the mandrel is fixed within the annular lumen, and illustrates in the figures the mandrel spaced apart from the shaft.

Therefore, Evard appears merely to be disclosing at col. 3, lines 38-39 that the mandrel is non-removable from the annular lumen.

The Examiner rejected claims 11, 13, 16-18, 51 and 56 under 35 USC §103(a) as being unpatentable over Shank et al. in view of Crowley and further in view of Berenstein et al., stating that Shank et al. discloses mandrel 10 comprised of a variable stiffness, non-metal material (see column 7, line 5) and Crowley teaches a metal guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than the proximal portions and Berenstein teaches a PVC or polyurethane catheter provided with added flexibility where the catheter is annealed. However, as discussed above, Crowley and Berenstein teach an annealed section which is made more flexible.

Moreover, Shank et al. does not disclose or suggest a mandrel having a solid core comprised of a non-metal material as required by claim 11, or a non-metal material mandrel formed of a polyetheretherketone polymeric material as in claims 19 and 51. Instead, in Shank et al. the body of the mandrel (i.e., guidewire corewire 10) is metallic. Although Shank et al. does disclose providing a polymeric Teflon coating on the metallic body, that coating does not form the mandrel's solid metal core, and similarly is not a non-metal material mandrel formed of a polyetheretherketone polymeric material (as in claim 51).

The Examiner rejected claim 12 under 35 USC §103(a) as being unpatentable over Hibbs et al. in view of Crowley and further in view of Berenstein et al., stating that Hibbs et al. discloses a mandrel 20 comprised of a variable stiffness, non-metal material, and

the material is polyamide and Crowley teaches a metal guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than the proximal portions and Berenstein teaches a PVC or polyurethane catheter provided with added flexibility where the catheter is annealed. However, as discussed above, Crowley and Berenstein teach an annealed section which is made more flexible.

Moreover, Applicants have carefully reviewed Hibbs et al. and can find no teaching or suggestion of a non-metal mandrel disposed in a catheter shaft lumen as required by claim 12. Instead, the element 20 referred to by the Examiner as being the mandrel, is the introducer itself formed of tubular body portion 24 and tubular tip portion 26, and the tubular members 24, 26 forming said introducer shaft have a catheter disposed therein, and thus are not disposed in a catheter shaft. Therefore, Hibbs does not disclose or suggest a non-metal material mandrel disposed in a catheter shaft.

In addition to other amendments, Applicants have amended claims 11, 19 and 51 to call for the mandrel having an annealed proximal section. Support for the amendment can be found on page 9, lines 11-13. Applicants have amended claim 11 to call for the mandrel having a non-metal solid core. Support can be found in Fig. 2. Applicants have amended claims 14 and 15 to call for the distal section of the mandrel extending to a location in the inflatable member, and proximal to the inflatable member, respectively. Support can be found on page 8, lines 5-6, disclosing that the mandrel 24 typically ends short of the inflatable member 20. Applicants have amended claims 16 and 64 to call for the mandrel being fusion bonded to the catheter shaft (and, in claim 64, compatible with the polymeric material of the catheter shaft). Support can be found on page 9, lines 19-

21. Applicants have amended claim 56 to call for the mandrel having a diameter tapering from the proximal to the distal end thereof. Support can be found on page 9, lines 9-10.

In light of the above amendments and remarks, applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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